IN THE CLAIMS:

Please cancel claims 1-4 in view of new claims 5-45 as shown in Attachment B without any prejudice or disclaimer to the subject matter expressed therein.

REMARKS

The specification is currently being amended to conform with the parent application, U.S. Patent Application 10/208,279, now U.S. Patent 6,699,464, to rename "octyl methoxycinnamate" to "octinoxate" in accordance with the U.S. Pharmacopeia and the USAN Council. The change was recognized in the Federal Register, Vol. 67, No. 119, June 20, 2002, pages 41821-41823, and was filed in the parent application on November 1, 2002.

On page 6, line 17, the "octyl" preceding "methoxycinnamate" was inadvertently left out. Basis for this inadvertent typographical error can be found in the same paragraph on page 6, line 20.

The re-naming of the compound from "octyl methoxycinnamate" to "octinoxate" does not affect the chemical properties of the composition, since they are both the same compound.

Claims 5-45 are currently pending in the present application. Applicants kindly request that claims 1-4 be cancelled and claims 5-45 be added without any prejudice or disclaimer to the subject matter expressed therein.

Additionally, Applicants thank the Examiner for her

consideration of this application and the claim amendment strategy during the telephone interview of October 5, 2004. The claims have been amended as discussed with the Examiner to cancel claims 1-4 and add new claims 5-45, relating to the same class of subject matter as claims 1-4, namely compositions and methods of making or using the same. The amendments to the specification and claims presented herein do not introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, the Examiner is respectfully requested to enter these amendments.

1. Double Patenting Rejection

The Office Action states, "Claims 1-4 are rejected under 35 U.S.C. 101, as claiming the same invention as that of claims 1-4 of prior U.S. Patent 6,669,464. This is a double patenting rejection."

RESPONSE

Applicants have cancelled the rejected claims 1-4, and submitted new claims 5-45 relating to the same class of subject matter as claims 1-4, but of a different scope. These new claims are not identical to those of U.S. Patent 6,699,464, removing the basis for the present statutory double patenting rejection.

CONCLUSION

Based upon the above remarks, the presently claimed subject

matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to allow all pending claims 5-45. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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ATTACHMENT A

On page 6, lines 13 - 23, please amend the specification as follows:

The compositions of the present invention include sunscreens which in combination with other ingredients provide a composition which has a SPF of at least 15. To provide a formula with a SPF value of not less than 15 usually requires the use of more than a single UVB sunscreen. Suitable UVB sunscreens for use in the compositions of the present invention include avobenzone, ~~methoxycinnamate~~ octinoxate, oxybenzone and octocrylene. Avobenzone additionally functions as the preferred UVA sunscreen, however it is not measured as a part of the SPF value. The amount of ~~octyl methoxycinnamate~~ octinoxate ranges from 1 percent to 10 percent, the amount of octocrylene ranges from 1 percent to 15 percent, and the amount of oxybenzone ranges from 0 percent to 10 percent by weight of the formulation. The amount of avobenzone in the formulation ranges from 1 percent to 5 percent.

On page 8, line 20 - page 9, line 3, please amend the specification as follows:

Sunscreens that provide maximum protection for UVB radiation without compromising stability include ~~octyl methoxycinnamate~~ octinoxate, oxybenzone, and octocrylate, or combinations thereof. ~~Octyl methoxycinnamate~~ Octinoxate has a preferred range of 4.0 percent to 7.5 percent, octocrylene has a preferred range of 6 percent to 10 percent, and oxybenzone has a preferred range of three percent to six percent by weight of the formulation. A sunscreen such as avobenzone can be used at lower amounts for protection from UVA radiation, such as 1 percent to 5 percent by weight of the formulation, with a preferred range of 2 percent to 3 percent by weight of the formulation.

On page 9, lines 11 - 21, please amend the specification as follows:

Next, the following ingredients, expressed in "parts" as percent by weight of ingredient by percent by weight formulation, are combined and heated to 65 degree C to form a uniform composition: 0 or 6.0 parts of oxybenzone, 9.0 parts of glyceryl monostearate, 6.5 parts of octyldodecyl stearoyl stearate, 2.45 parts of quaternium-26, 5.0 parts of glyceryl stearate and PEG-100 stearate, 3.9 parts of glyceryl dialaurate, 0.9 part of diethylaminoethyl stearate, 2.3 parts of cetostearyl alcohol, 2.2 parts of ceteareth-20, 0.5 part of dimethicone, 0.35 part of polysorbate 80, 1.4 parts of stearyl alcohol, 3.0 parts of avobenzone, 0.05 part of propylparaben, 0.1 part of propyl gallate, 1.0 part of a squalane and ubiquinone solution, and 7.5 parts ~~octyl methoxycinnamate~~ <u>octinoxate</u>; this is added to the second solution to achieve a uniform combined composition.

On page 10, line 14 - page 11, line 1, please amend the specification as follows:

Composition for Treating Hyperpigmentation

with UVA and UVB sunscreens

Ingredients	Percentage (%W/W)
Hydroquinone	4.00
Avobenzone	3.00
Ceteareth-20	2.20
Cetostearyl Alcohol	2.30
Citric Acid	1.20
Diethylaminoethyl Stearate	0.90
Dimethicone	0.50
Edetate Disodium	0.10
Glyceryl Dilaurate	3.90
Glyceryl Monostearate	9.00
Glyceryl Stearate (and) PEG-100 Stearate	5.00
Hydroxyethyl Cellulose	0.30
Methylparaben	0.05
Octyldodecyl Stearoyl Stearate	6.50
~~Octyl Methoxycinnamate~~ Octinoxate	7.50
Polysorbate 80	0.35
Propylene Glycol	3.40

Propyl Gallate	0.10
Propylparaben	0.05
Purified Water	41.25
Quanternium-26	2.45
Rumex Extract (as Tyrostat-20)	1.00
Sodium Metabisulfite	0.05
Sodium PCA, 50% solution	2.50
Squalane (and) Ubiquinone	1.00
Stearyl Alcohol	1.40

On page 12, lines 4 - 5, please amend the specification as follows:

Next, chemical stability of ~~Octyl Methoxycinnamate~~ Octinoxate was determined using a suitable HPLC assay. The %W/W results obtained are shown in Table 3 below:

On page 12, lines 8 - 10, please amend the specification as follows:

The results show that ~~octyl methoxycinnamate~~ octinoxate remained chemically active after exposure of the formulation to high and low temperatures for 30 and 90 days.

On page 13, line 10 - page 14, line 3, please amend the specification as follows:

Composition for Treating Hyperpigmentation

with UVA and UVB Sunscreens

Ingredients	Percentage (%W/W)
Hydroquinone	4.00
Avobenzone	3.00
Ceteareth-20	2.20
Cetostearyl Alcohol	2.30
Citric Acid	1.20
Diethylaminoethyl Stearate	0.90
Dimethicone	0.50
Edetate Disodium	0.10
Glyceryl Dilaurate	3.90
Glyceryl Monostearate	9.00
Glyceryl Stearate (and) PEG-100 Stearate	5.00
Hydroxyethyl Cellulose	0.30
Methylparaben	0.05
Octyldodecyl Stearoyl Stearate	6.50
~~Octyl Methoxycinnamate~~ Octinoxate	7.50
Oxybenzone	6.00
Polysorbate 80	0.35
Propylene Glycol	3.40

Propyl Gallate	0.10
Propylparaben	0.05
Purified Water	35.25
Quanternium-26	2.45
Rumex Extract (as Tyrostat-20)	1.00
Sodium Metabisulfite	0.05
Sodium PCA, 50% solution	2.50
Squalane (and) Ubiquinone	1.00
Stearyl Alcohol	1.40

On page 15, lines 10 - 11, please amend the specification as follows:

The results show that ~~octyl methoxycinnamate~~ <u>octinoxate</u> remained active after exposure of the formulation to high and low temperatures for 30 to 90 days.

ATTACHMENT B

Claims 1-4. (Canceled)

Claim 5. (New) A dermatological composition for treating human skin, consisting essentially of:

1) a therapeutic active ingredient that is hydroquinone;

2) sunscreens selected from the group consisting of avobenzone, octinoxate, oxybenzone, octocrylene, and mixtures thereof; and

3) at least one dermatologically acceptable excipient.

Claim 6. (New) The composition of claim 5, wherein said hydroquinone is present in said composition at about 1 to about 10% by weight.

Claim 7. (New) The composition of claim 6, wherein said hydroquinone is present in said composition at about 2 to about 4% by weight.

Claim 8. (New) The composition of claim 5, wherein said sunscreens are present in said composition at about 13 to about 27% by weight.

Claim 9. (New) The composition of claim 8, wherein said avobenzone is present in said composition at about 1 to about 5% by weight.

Claim 10. (New) The composition of claim 8, wherein said octinoxate is present in said composition at about 1 to about 10% by weight.

Claim 11. (New) The composition of claim 8, wherein said oxybenzone is present in said composition at about 1 to about 10% by weight.

Claim 12. (New) The composition of claim 8, wherein said octocrylene is present in said composition at about 1 to about 15% by weight.

Claim 13. (New) The composition of claim 5, wherein said at least one dermatologically acceptable excipient is selected from the group consisting of a rumex extract, an antioxidant, an emulsifier, an emollient, a moisturizer, water, and mixtures thereof.

Claim 14. (New) The composition of claim 13, wherein said rumex extract is selected from the group consisting of Tyrostat-20, Tyrostat-21, and mixtures thereof.

Claim 15. (New) The composition of claim 13, wherein said antioxidant is present in said composition at about 0.02 to about 1% by weight.

Claim 16. (New) The composition of claim 13, wherein said at least one antioxidant is selected from the group consisting of propyl gallate, sodium metabisulfite, and mixtures thereof.

Claim 17. (New) The composition of claim 13, wherein said emulsifier and emollient are present in said composition at about 20 to about 50% by weight total.

Claim 18. (New) The composition of claim 13, wherein said emulsifier and emollient are selected from the group consisting of ceteareth-20, cetostearyl alcohol, diethylaminoethyl stearate, glyceryl dilaurate, glyceryl monostearate, glyceryl stearate, PEG-100 stearate, octyl-dodecyl stearoyl stearate, polysorbate 80, quaternium-26, stearyl alcohol, and mixtures thereof.

Claim 19. (New) The composition of claim 13, wherein said moisturizer is present in said composition at about 0.2 to about 15% by weight.

Claim 20. (New) The composition of claim 13, wherein said moisturizer is selected from the group consisting of sodium PCA, dimethicone, cyclomethicone, propylene glycol, polysiloxane derivatives, ubiquinone, and mixtures thereof.

Claim 21. (New) The composition of claim 5, wherein said composition provides UVA, and UVB protection with a SPF value of at least 15.

Claim 22. (New) The composition of claim 5, wherein said composition is formed as a cream.

Claim 23. (New) The composition of claim 5, wherein said composition is physically and chemically stable for a prolonged period of time.

Claim 24. (New) The composition of claim 5, wherein said composition has a smooth texture, a homogenous appearance, and is readily absorbable by said human skin.

Claim 25. (New) The composition of claim 5, wherein said composition is tolerated by skin to which it is applied.

Claim 26. (New) The composition of claim 5, wherein said composition is contained in a glass or coated aluminum tube container.

Claim 27. (New) A method for treating hyperpigmentation in a human, comprising:

administering to a human suffering from hyperpigmentation a dermatological composition consisting essentially of:

1) a therapeutic active ingredient that is hydroquinone;

2) sunscreens selected from the group consisting of avobenzone, octinoxate, oxybenzone, octocrylene, and mixtures thereof; and

3) at least one dermatologically acceptable excipient.

Claim 28. (New) The method of claim 27, wherein said method reduces darkening skin of said human.

Claim 29. (New) The method of claim 27, wherein administration of said composition does not produce redness, sensitization, or burning in said human.

Claim 30. (New) A method of providing SPF of at least 15 to skin of a human, said method comprising:

administering to the skin of a human in need thereof a dermatological composition to provide a SPF of at least 15 to said skin of said human, wherein said composition consists essentially of:

1) a therapeutic active ingredient that is hydroquinone;

2) sunscreens selected from the group consisting of avobenzone, octinoxate, oxybenzone, octocrylene, and mixtures thereof; and

3) at least one dermatologically acceptable excipient.

Claim 31. (New) The method of claim 30, wherein said composition provides UVA and UVB protection to said skin of said human.

Claim 32. (New) A method of reducing irritation in skin of a human produced by topical application of a therapeutic agent, said method comprising:

administering to the skin of a human a dermatological composition comprising:

1) a therapeutic active ingredient that is hydroquinone;

2) sunscreens selected from the group consisting of avobenzone, octinoxate, oxybenzone, octocrylene, and mixtures thereof;

3) at least one ether, alcohol, or ester of a stearate;

4) a polysiloxane derivative;

5) sodium PCA; and

6) at least one additional dermatologically acceptable excipient.

Claim 33. (New) The composition of claim 32, wherein said at least one ether, alcohol, or ester of a stearate is selected from the group consisting of ceteareth-20, cetostearyl alcohol, diethylaminethyl stearate, glyceryl dilaurate, glyceryl monostearate, glyceryl stearate, PEG-100 stearate, octyl-dodecyl stearoyl stearate, polysorbate 80, quaternium-26, stearyl alcohol, and mixtures thereof.

Claim 34. (New) The composition of claim 32, containing about 1 to about 10% by weight of said sodium PCA.

Claim 35. (New) A process for preparing a dermatological composition for treating human skin, said process comprising:

1) dissolving a first antioxidant in water having a temperature of about 75 ^{0}C to form a first solution;

2) cooling said first solution to form a cooled first solution;

3) adding at least one first moisturizer and a therapeutic active ingredient that is hydroquinone to said cooled first solution to form a second solution;

4) preparing an uniform composition comprising at least one emulsifier, at least one emollient, at least one second moisturizer, a second antioxidant, and sunscreens selected from the group consisting of avobenzone, octinoxate, oxybenzone, octocrylene, and mixtures thereof;

5) adding said uniform composition to said second solution to obtain an uniform combined composition;

6) cooling said uniform combined composition;

7) adding a third antioxidant to said uniform combined composition; and

8) recovering a dermatological composition for treating human skin.

Claim 36. (New) The process of claim 35, wherein said first antioxidant and said third antioxidant are the same.

Claim 37. (New) The process of claim 36, wherein said first and said third antioxidant are sodium metabisulfite.

Claim 38. (New) The process of claim 35, wherein said water is heated and mixed to a temperature of about 75 ^{o}C prior to said process step 1.

Claim 39. (New) The process of claim 35, wherein said heating and mixing is conducted under a vaccum.

Claim 40. (New) The process of claim 35, wherein said at least one first moisturizer is selected from the group consisting of propylene glycol, sodium PCA, and mixtures thereof.

Claim 41. (New) The process of claim 35, wherein said uniform composition is prepared at a temperature of not less than about 65 ^{0}C.

Claim 42. (New) The process of claim 35, wherein said at least one emulsifier and emollient are selected from the group consisting of ceteareth-20, cetostearyl alcohol, diethylaminoethyl stearate, glyceryl dilaurate, glyceryl monostearate, glyceryl stearate, PEG-100 stearate, octyl-dodecyl stearoyl stearate, polysorbate 80, quaternium-26, stearyl alcohol, and mixtures thereof.

Claim 43. (New) The process of claim 35, wherein said at least one second moisturizer is selected from the group consisting of dimethicone, ubiquinone, and mixtures thereof.

Claim 44. (New) The process of claim 43, wherein said second antioxidant is propyl gallate.

Claim 45. (New) The process of claim 35, wherein said process step 8) further comprises cooling said uniform combined composition to recover said dermatological composition for treating human skin.